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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,818	08/03/2000	Cynthia C. Bamdad	M1015/7013	9436

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EXAMINER
TURNER, SHARON L

ART UNIT	PAPER NUMBER
1647	5

DATE MAILED: 03/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/631,818	Bamdad et al.
Examiner	**Art Unit**
Sharon L. Turn r, Ph.D.	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 8-17-01

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-378 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-378 are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. The preliminary amendment filed 8-17-01 has been entered into the record and has been fully considered.

2. Claims 1-378 are pending.

Improper Markush

3. Prior to setting forth the restriction requirement, it is pointed out that applicants have presented instant claims in improper Markush format, see Ex parte Markush, 1925 C.D. 126, In re Weber, 198 USPQ 334 and MPEP 803.02 and 806.04. The claims are improperly set forth as the genus claims encompassing multiple products, as identified and claimed, fail to share the characteristics of a genus, i.e., a common utility and a substantial structural feature essential to the disclosed utility. Alternatively, the claims define multiple structurally distinct compounds capable of different use, with different modes of operation, different function and different effects. A reference against one of the claimed components or methods would not be a reference against the other. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims define inventions which are not proper species.

4. The examiner notes the presence of multiple dependent claims and antecedent basis problems in the pending claims.

Election/Restriction

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-71, 111-135, and 267 drawn respectively to a kit comprising two articles and a plurality of binding species, classified for example in class 536, subclass 23.1.

II. Claims 72-93 drawn to a composition, classified for example in class 530, subclass 300.

III. Claims 94-110 and 136-142 are drawn to a method, classified for example in class 435, subclass 6.

IV. Claims 143, and 147-149 drawn to a method of forming with surfactant, classified for example in class 434, subclass 524.

V. Claim 144 drawn to a method of forming with a carboxylate, classified for example in class 436, subclass 528.

VI. Claim 145 drawn to a method of forming not during formation of colloid, classified for example in class 436, subclass 533.

VII. Claim 146 drawn to a method of forming in suspension, classified for example in class 436, subclass 534.

VIII. Claims 150-153 drawn to a method of providing a linker and drug, classified for example in class 436, subclass 532.

IX. Claims 154-164 drawn to a method of monitoring cellular formation of aggregates, classified for example in class 436, subclass 519.

X. Claims 165-169 drawn to a method of forming a solution and detecting aggregation, classified for example in class 435, subclass 805.

XI. Claims 170-174, and 263-265 drawn to a system, classified for example in class 436, subclass 500.

XII. Claims 175-184, 226-230, 234, and 268-69 drawn to a method of providing articles and exposing samples, classified for example in class 436, subclass 16.

XIII. Claims 185-216, 231-233 drawn to a method of exposing samples to candidate drugs, classified for example in class 436, subclass 105.

XIV. Claims 217-225 drawn to a method of determining interactions, classified for example in class 435, subclass 961.

XV. Claims 235-248 drawn to a method of forming a composition with magnetic beads and exposing to samples, classified for example in class 436, subclass 173.

XVI. Claims 249-250 drawn to a composition comprising an electronic signaling entity, classified for example in class 435, subclass 285.2.

XVII. Claims 251-256 drawn to a method of converting binding species to aggregate forming species, classified for example in class 435, subclass 272.

XVIII. Claims 257-258 drawn to a method of allowing binding, classified for example in class 435, subclass 252.4.

XIX. Claims 259 drawn to a method of detecting aggregation characteristic of neurodegenerative disease, classified for example in class 435, subclass 368.

XX. Claims 260-261, 266 drawn to an article with signaling entity capable of binding an aggregate forming species, classified for example in class 435, subclass 181.

XXI. Claim 262 drawn to a kit comprising an article and a plurality of binding species, classified for example in class 536, subclass 24.31.

XXII. Claims 270-274 drawn to a method of administration to a human, classified for example in class 514, subclass 2.

XXIII. Claims 275 drawn to a beta amyloid composition, classified for example in class 530, subclass 300.

XXIV. Claims 276, 279-282, 299-304, and 308-309 drawn to a method of determining immobilization of a colloid particle, classified for example in class 435, subclass 326.

XXV. Claim 277 drawn to a kit with a candidate agent, classified for example in class 536, subclass 23.1.

XXVI. Claim 278 drawn to a method of determining immobilization other than nucleic acid, classified for example in class 435, subclass 7.1.

XXVII. Claims 283-298 drawn to a method a method of providing an immobilized emissive or absorptive species to form a colloid derivatized with a self assembling monolayer solution and detecting aggregation, classified for example in class 435, subclass 287.9.

XXVIII. Claims 305-307 drawn to a method of exposing with an enzyme to facilitate linkage, classified for example in class 435, subclass 183.

XXIX. Claim 310 drawn to a method of determining immobilization wherein an analyte is fastened to a chemical or biological species, classified for example in class 436, subclass 539.

XXX. Claims 311-315, 317 and 319 drawn to a method of determining disruption of binding, classified for example in class 436, subclass 541.

XXXI. Claims 316-19 drawn to a method of forming a solution and detecting aggregation, classified for example in class 436, subclass 540.

XXXII. Claims 320-334 drawn to a method of forming a solution and detecting aggregation, classified for example in class 436, subclass 503.

XXXIII. Claims 335-350 drawn to a biphasic method with two different sets of conditions, classified for example in class 436, subclass 167.

XXXIV. Claims 351-364 drawn to a method of assessing a candidate drug and contacting under a second set of conditions, classified for example in class 435, subclass 91.2.

XXXV. Claims 365-366 drawn to a method of determining stage of disease, classified for example in class 530, subclass 412.

XXXVI. Claims 367-371 drawn to a method of determining the extent of aggregation with a candidate drug forming a solution and detecting aggregation, classified for example in class 435, subclass 808.

XXXVII. Claim 372, and 374-75 drawn to a method of determining the extent of aggregation in 1 minute, classified for example in class 435, subclass 177.

XXXVIII. Claims 373 drawn to a method of determining the extent of aggregation of a neurodegenerative disease aggregate forming species, classified for example in class 435, subclass 968.

XXXIX. Claims 376-378 drawn to a method of determining the extent of aggregation with a candidate drug forming a solution and detecting aggregation, classified for example in class 435, subclass 808.

6. The inventions are distinct, each from the other because of the following reasons:

7. Inventions I, II, XI, XVI, XX, XXI, XXIII, and XXV are related as products. The products are distinct each from the other as the products are comprised of divergent structural components which exhibit different effects and functions and are capable of different use. For example the components include nucleic acids, antibodies, peptides, cells, organisms, and inorganic compounds.

8. Inventions III-X, XII-XV, XVII-XIX, XXII, XXIV, and XXVI-XXIX are related as processes. The processes are distinct each from the other as the processes differ in reagents, steps, functions, effects and outcomes.

9. Inventions I, II, XI, XVI, XX, XXI, XXIII, XXV and III-X, XII-XV, XVII-XIX, XXII, XXIV, XXVI-XXIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are comprised of different reagents as claimed, are assembled via different methods comprising different steps, reagents and outcomes, and the products and processes are capable of different modes of operation, function and effects as evidenced by the claims.

10. Claims 1, 72, 94, 111, 143-146, 150, 154, 165, 170, 173, 175, 185, 217, 235, 249, 251, 257, 259, 260, 262, 270, 275, 276-279, 283, 305, 310, 311, 316, 320, 335, 351, 365, 367, 372, 373 and 376 are generic to a plurality of disclosed patentably distinct species comprising generic/subgeneric/classes/families of molecules selected from A) binding species, B) articles, C) candidate drugs, D) colloid/particle, E) chemical compounds, F) biological compounds, G) particles, H) aggregate-forming/aggregating species/monolayers, I) fastening mechanism/alteration/linkage/linker, J) a sample and K) a signalling entity/device/molecule.

Applicant is required under 35 U.S.C. 121 to designate a single molecular embodiment for each of the above classes of molecules which pertain to the elected invention as set forth in the claims of the elected group, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A proper election would include a designated Group, for example Group I and a designated molecular embodiment for each of the classes of molecules pertaining to the claims of the elected group. For example, Group I would require the designation of a particular molecular embodiment corresponding to an article, a binding species, an aggregate forming species, a

candidate drug, a colloid/particle, and a signalling entity, to which the initial search will be restricted.

Applicant's are encouraged to include a detailed description of the particular molecular kit, composition, article, method or system that is elected.

11. The inventions are distinct, each from the other because of the following reasons:

12. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because the products indicated as Groups I-XXXIX and species A-J constitute patentably distinct inventions for the following reasons. Each of the products (including reagents designated in the claimed methods) has a unique structural feature which requires a unique search of the prior art. The inventions indicated as A-K differ in structure and function as they are composed of divergent chemicals, nucleic acids, amino acids, antibodies, organic and inorganic molecules and are differentially able to hybridize, bind or mediate biological functions. A reference to one element would not constitute a reference to another. In addition, searching all of the molecules in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because the indicated searches are not co-extensive.

13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

14. Because these inventions are distinct for the reasons given above and the search required for any Group is not required for any other Group, restriction for examination purposes as indicated is proper.

15. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

16. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated groups I-XXXIX and a single molecular embodiment for each of designated classes of molecules which correspond to the claims of the elected group. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups.

Applicant's are further advised that a reply to this requirement must include an identification of the embodiments of A-K that are elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. If claims are added after the election, applicant must indicate which are readable upon the elected invention.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

18. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
February 28, 2002

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